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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,596	01/24/2002	Douglas C. Shepard	01-531	2926

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,596

Applicant(s)

SHEPARD, DOUGLAS C.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 25, 26 and 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11-24 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8-11-03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 1-25-05 is acknowledged.

In the previous office action, claim 25 which is drawn to the non-elected species (enzyme that converts hydrocortisone to cortisone) was inadvertently included in the prosecution.

Claims included in the prosecution are 1, 11-24 and 27.

In view of applicant's amendment to the claims, the previous 102 rejections are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 13-16, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson or Antwerp, Forster by themselves or in combination further in view of Pinchuk (5,741,331).

As pointed out in the previous action, Hendrickson et al disclose devices wherein enzymes catalase and papain are immobilized on the surfaces. This layer is further coated with a polymer (note columns, 4, 7-9 and claims 1 and 9).

Antwerp discloses indwelling catheters coated with fibrinolytic enzymes. The enzymes in turn are encapsulated and bonded to the surface of the catheter (columns 2-6 and claims).

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Forster discloses immobilized urokinase on polytetrafluoroethylene vascular prosthesis (note page 130).

These references however, do not teach the use of claimed block copolymer comprising polybutylene and acrylates or vinyl aromatics.

Pinchuk while teaching implantable medical devices teaches that polymeric material made from block copolymers of polyolefin and styrene or acrylate is biostable and crack-resistant when implanted in vivo (abstract, col. 1, line 6 through col. 2, line 41, examples and claims).

The use of polymeric material made from block copolymers of polyolefin and styrene or acrylate in the medical device of Sivan would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Pinchuk teaches that these block copolymers are biostable and crack-resistant when implanted in vivo.

3. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendrickson or Antwerp or Forster by themselves or in combination in further combination with Pinchuk (5,741,331) as set forth above, further in view of applicant's statements of prior art.

The teachings of Hendrickson, Antwerp, Forster and Pinchuk have been discussed above. What is lacking in these references is the teaching of immobilizing the enzymes on the medical article through antibody antigen interactions or by nucleic acid hybridization reactions. Applicant on page 5, paragraph 0029 indicates that these non-covalent protein-binding techniques are known the art. It would have been obvious to use non-covalent attachment techniques to

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immobilize the enzymes taught by Hendrickson or Forster or Antwerp with the expectation of obtaining similar binding would have been obvious to one of ordinary skill in the art since these techniques are art known binding techniques, especially known to be used to coat medical articles.

4. Claims 1, 11-16, 19-24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan cited in the previous action, in combination with Pinchuk (5,741,331).

Sivan discloses an intravascular apparatus wherein nitric oxide synthase is covalently attached to the carrier. The enzyme either chemically attached to the stent or alternatively entrapped within a polymeric hydrogel that covers the stent. The polymeric material includes polymers and copolymers such as polyethylene, polypropylene, polyacrylic acid and others (col. 3, line 41 through col. 5, line 9 and claims 1 and 4). What is lacking in Sivan is the use of claimed block copolymer comprising polybutylene and acrylates or vinyl aromatics.

Pinchuk while teaching implantable medical devices teaches that polymeric material made from block copolymers of polyolefin and styrene or acrylate is biostable and crack-resistant when implanted in vivo (abstract, col. 1, line 6 through col. 2, line 41, examples and claims).

The use of polymeric material made from block copolymers of polyolefin and styrene or acrylate in the medical device of Sivan would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Pinchuk teaches that these block copolymers are biostable and crack-resistant when implanted in vivo.

5. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sivan in combination with Pinchuk (5,741,331), further in combination with applicant's statements of prior art.

The teachings of Sivan and Pinchuk have been discussed above. What is lacking in these references is the teaching of immobilizing the enzymes on the medical article through antibody-antigen interactions or by nucleic acid hybridization reactions. Applicant on page 5, paragraph 0029 indicates that these non-covalent protein-binding techniques are known the art. It would have been obvious to use non-covalent attachment techniques to immobilize the enzymes taught by Sivan with the expectation of obtaining similar binding would have been obvious to one of ordinary skill in the art since these techniques are art known binding techniques, especially known to be used to coat medical articles.

a. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK